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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,941	08/31/2001	Shirley I. Miekka	CI-003	8965

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
SMITH, JOHNNIE L	

ART UNIT	PAPER NUMBER
2881	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,941	MIEKKA ET AL.	
	Examiner	Art Unit	
	Johnnie L Smith II	2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0518, 0826, 0225, 0401, 0605, 0925
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-9, 58-59, 94-97 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,171,549 (Kent). In reference to claims 1-3, 58, and 59, Kent discloses a method for sterilizing a preparation sensitive to radiation, the method comprising steps of adding to the preparation at least one stabilizer in an amount effective to protect the preparation from the radiation, reducing the residual solvent content of said preparation containing albumin to a level effective to protect said preparation containing albumin from said radiation, or reducing the temperature of the preparation containing albumin to a level effective to protect the preparation containing albumin from the radiation, and irradiating the preparation

containing albumin with a suitable radiation at an effective rate for a time effective to sterilize said preparation (column 2 lines 24-67).

3. In reference to claims 4 and 5, Kent discloses a method for sterilizing a preparation containing albumin that is sensitive to radiation, the method comprising steps of, applying to said preparation containing albumin at least one stabilizing process selected from the group consisting of reducing the residual solvent content of said preparation containing albumin, reducing the temperature of said preparation containing albumin, or adding at least one stabilizer to said preparation containing albumin, and irradiating said preparation containing albumin with a suitable radiation at an effective rate for a time effective to sterilize said preparation containing albumin, wherein said at least one stabilizing process and the rate of irradiation are together effective to protect said preparation containing albumin from said radiation (column 2 lines 24-67, see claims). Kent teaches the product being a protein, and wherein the preparation containing albumin comprises at least one biological material or at least one tissue selected from the group consisting of heart valves, skin, bone, blood vessels, ligaments, nerves, and corneas (column 13 lines 4-38). In reference to claims 6-9, while Kent discloses the recited solvents (example 9). In reference to claims 43-52, Kent teaches the use of UV, Gamma, or ionizing radiations (Background or invention).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 10-57 and 60-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,171,549 (Kent). Regarding claims 10-18 Kent fails to disclose the specific dose rate as being claimed, but shows the usage of various dose rate (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have various dose rates, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to, based on the material being analyzed. *In re Alter, 220 F.2d 454, 456, 105 USPQ 233, 235 Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.*

7. In reference to claims 19-22, while Kent fails to clearly disclose the specific environment by which to maintain the albumin, Kent, however, does show an experiment wherein the contents of flasks were observed and a visual determination where made following the absorption of oxygen or exposure to ambient air, therefore, it would have been obvious to one of ordinary skill in the art to use such a variety of environments since it is understood from the experiment disclosed in Kent that some form of controlled environment was utilized.

8. In reference to claims 23-30 and 60-66, Kent fails to disclose the specific residual solvent percentage. Kent, however, does teach a range of percentages; therefore, it would have been obvious to one of ordinary skill in the art to determine the most effective percentage since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to, based on Kent teachings of percentages within the said range. *In*

re Alter, 220 F.2d 454, 456, 105 USPQ 233, 235 Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

9. In reference to claims 31-42, while Kent fails to clearly disclose the recited stabilizers, Kent does disclose adding free radicals and other materials (column 3 lines 3-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to use such stabilizers for the purpose of reducing damage to the biological material being irradiated.

10. In reference to claims 54-57, while Kent fails to teach all of the specific irradiation conditions, Kent, however, does teach irradiating the product in ambient and at or near room temperature, therefore, it would have been obvious to one of ordinary skill in the art to have said variety of irradiation conditions, since as shown in Kent, a variety of conditions may be utilizes.

11. In reference to claims 67-68, Kent teaches the preparation containing albumin comprising at least protein selected from a group including factor VIII (claim 15).

12. In reference to claims 70-77, Kent fails to disclose the specific protein concentration percentage, but does teach percentages within the said range, therefore, it would have been obvious to one of ordinary skill in the art to

determine the most effective percentage from the teaching of Kent since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. One would have been motivated to, based on Kent teachings of percentages within the said range. *In re Alter, 220 F.2d 454, 456, 105 USPQ 233, 235 Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation..*

13. In reference to claims 79-93, applicant discloses a wide variety of intended uses for the said invention. Kent teaches an invention that can be used to treat a wide variety products that require sterilization, therefore, it would be obvious to one of ordinary skill in the art to modify the teachings of Kent for the purpose of optimizing them for a variety known of treatment methods.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnnie L Smith II whose telephone number is 571-272-2481. The examiner can normally be reached on Monday-Thursday 7-4 P.M. and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R Lee can be reached on 571-272-2477. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLSII

Johnnie L Smith II
Examiner
Art Unit 2881

JOHN R. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800